

STATE OF NEW YORK
SUPREME COURT : COUNTY OF ERIE

COUNTY OF ERIE,

Plaintiff,

-VS-

MEMORANDUM DECISION
Index No. 2005-2439

ABBOTT LABORATORIES, INC.,
ET AL.,

Defendants.

APPEARANCES:

(see attached appearance list)

FAHEY, EUGENE M., J.S.C.

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ACTIONS & PROCEEDINGS
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The County of Erie sued seventy-seven (77) manufacturers of pharmaceuticals for damages sustained by allegedly fraudulent reporting of "average wholesale price[s]" on prescription drugs paid for under Medicaid. The case was remanded to this Court in January 2006 by the Hon. Patti Saris of the United States District Court for the District of Massachusetts. After this Court denied without prejudice a motion to sever the case as to non-diverse Defendants, numerous Defendants filed motions to dismiss. Specifically, seventy-six (76) Defendants filed a Joint Motion to Dismiss; TAP Pharmaceuticals, Inc. filed a separate Motion to Dismiss; and twenty-seven (27) Defendants filed ten (10) separate briefs and/or other supplemental pleadings. Plaintiff opposed all of the motions except that brought by TAP Pharmaceuticals; the latter motion was therefore granted on May 2, 2006. Oral argument was held on all other motions on that date, and the Court reserved decision.

Upon due consideration of all papers submitted and arguments heard, the Court hereby determines:

- 1) the Joint Motions to Dismiss are granted in part, by dismissing the second cause of action based on Social Services Law § 366-b, the fourth cause of action under General Business Law § 349, and the sixth cause of action alleging fraudulent concealment, but are otherwise denied;
- 2) the separate applications of the so-called "Erie-Only Defendants" are denied;
- 3) the separate application of Genentech, Inc. is denied;
- 4) the separate application of "Certain Defendants" (Alcon Laboratories, Inc., Biogen Idec Inc., Endo Pharmaceuticals Inc., MedImmune, Inc., Takeda Pharmaceuticals North America, Inc., and UCB, Inc.) is denied;
- 5) the separate application of Novartis Pharmaceuticals Corporation (NPC) and certain other Defendants is denied as to NPC and Par Pharmaceutical Inc., but granted as to Agouron Pharmaceuticals, Inc. (Agouron), and Greenstone, LTD (Greenstone), subsidiaries of Pfizer, Inc., with leave to Plaintiff to replead against Agouron and/or Greenstone within thirty (30) days of service of notice of entry of an order;
- 6) the separate application of Immunex, Inc. is granted, dismissing all causes of action against Immunex, with leave to Plaintiff to replead within thirty (30) days of service of notice of entry of an order, as to any other Immunex drugs and/or liability for actions of Amgen, if any;

- 7) the separate application of Purdue Pharma, L.P. is granted, dismissing all causes of action against it with leave to Plaintiff to replead within thirty (30) days of service of the notice of entry of an order;
- 8) the separate application by Hoffmann-LaRoche Inc. and Roche Laboratories, Inc. is granted in part and denied in part, and any claims against Hoffmann-LaRoche Inc. only are dismissed, with leave granted to Plaintiff to replead within thirty (30) days of service of notice of entry of an order;
- 9) the separate application of AstraZeneca Pharmaceuticals, LP is granted in part and denied in part, as detailed herein;
- 10) the separate application of Bayer Corporation is granted in part and denied in part, as detailed herein;
- 11) the separate application of Sandoz Inc. is denied.

ALL MOTIONS

A. BACKGROUND

The County of Erie brought this action to "recover monetary damages, impose civil penalties, disgorge profits and for treble and punitive damages as a consequence of fraudulent and misleading schemes perpetuated by the defendants since 1992" (Pennock Affirm., Exhibit A, Verified Complaint [hereinafter VC] ¶ 1).

The Medicaid program, which provides health insurance coverage for the poor and the disabled, is a grant-in-aid program some percentage of which is paid for by the federal government through reimbursement to the States (*see* Quinn Affirm. ¶ 8; 42 USC 1396 et seq.). In turn, the State of New York administers the Medicaid program, sets reimbursement rates

subject to both State and federal law, and charges local social service districts (in this case, Erie County), twenty-five percent (25%) of the costs for covered drugs for their residents (*see* VC ¶ 3, citing Social Services Law [SSL] §§367-a, 368-a, 368-b).¹ This lawsuit concerns only prescription drugs dispensed by pharmacies in Erie County to its Medicaid beneficiaries.

Under federal regulations, State Medicaid agencies are required to assure that they do not pay more for drugs prescribed under Medicaid than the limits on the prices for such drugs imposed by the Center for Medicare and Medicaid Services (hereinafter CMS) (*see* 42 CFR 447.333 [b] [2]). (CMS was formerly known as the Health Care Financing Administration [hereinafter HCFA]). For multiple source drugs (otherwise known as generic drugs), CMS is required to determine a Federal upper price limit (hereinafter “FUL”) when commercial publications indicate that there are at least three suppliers of the same therapeutically equivalent generic drug (*see* 42 CFR 447.332). The CMS sets FULs at one-hundred and fifty (150) percent of the published price in any national compendia for the least costly therapeutic equivalent for that particular drug for any manufacturer (*see* CFR 447.332 [b]; 52 Fed Reg 28648 et seq. [July 31, 1987]). Once set, the FUL for a particular generic drug applies to every manufacturer (*id.*).

For many drugs, however, there is no FUL set.² In such cases, the drugs are reimbursed at the lower of “estimated acquisition cost” or the pharmacy’s “usual and customary price charged

¹ Note that the Verified Complaint elsewhere indicates that local social service districts pay one-half of the district’s costs for drugs covered by Medicaid, or 25% of the total cost of Medicaid (*see* VC ¶ 106). It is unclear which of the two allegations is correct, and the cited statutes do not clarify the matter, which is, nonetheless, not of current relevance.

² The Verified Complaint does not indicate which Defendants’ drugs have an FUL.

to the general public" (Social Services Law [SSL] § 367-a [9] [b] [ii]), plus a dispensing fee (*see id.* § 367-a [9] [d]).³

³ Section 367-a(9) of the SSL sets the reimbursement rates for prescription drugs under Medicaid. As of 1990, that section provided that the department (now the Department of Health) was required to "establish payment levels for multi-source prescription drugs consistent with federal law and regulations" (SSL former § 367-a [9], added by 1990 NY Session Laws c. 190, § 378). Apparently there was no specific reimbursement formula for payment for brand name drugs. After 1994, that section provided for more specific formulas, and has been amended too frequently to warrant reciting in this decision. In fact, since the parties submitted their motion papers, the section has been amended to alter the reimbursement formula, as noted in the text. The section now provides in pertinent part:

9. Notwithstanding any inconsistent provision of law or regulation to the contrary, for those drugs which may not be dispensed without a prescription * * * and for which payment is authorized * * *, payments under this title shall be made at the following amounts:

* * *

(b) for drugs dispensed by pharmacies:

(i) if the drug dispensed is a multiple source prescription drug for which an upper limit has been set by the federal centers for medicare and medicaid services, an amount equal to the specific upper limit set by such federal agency for the multiple source prescription drug, and

(ii) if the drug dispensed is a multiple source prescription drug or a brand-name prescription drug for which no specific upper limit has been set by such federal agency, *the lower of the estimated acquisition cost of such drug to pharmacies, or the dispensing pharmacy's usual and customary price charged to the general public.* For sole and multiple source brand name drugs, *estimated acquisition cost means the average wholesale price of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the department, less thirteen and twenty-five hundredths of one percent thereof, and updated monthly by the department; * * *. For multiple source generic drugs, estimated acquisition cost means the lower of the average wholesale price of a prescription drug based on the package size dispensed from, as reported by the prescription drug pricing service used by the department, less twenty percent thereof, or the maximum acquisition cost, if any, established pursuant to paragraph (e) of this subdivision; * * *.*

* * * (d) In addition to the amounts paid pursuant to paragraph (b) of this subdivision to pharmacies for those drugs which may not be dispensed

“Estimated Acquisition Cost” (hereinafter “EAC”) is further defined by statute as, for brand name drugs, “the average wholesale price of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the department, less thirteen and twenty-five hundredths of one percent thereof” (SSL § 367-a [9][b][ii]). In other words, brand name drugs are reimbursed by AWP minus 13.25% (*id.*)

For generic drugs, the EAC is defined as the lower of AWP less twenty (20) percent or the “maximum acquisition cost if, any” established by the State (*id.* § 367-a [9][b][ii], [e] [defining “maximum acquisition cost”; see fn.3, *supra*]). Thus, pharmacy-prescribed multi-

without a prescription, as required by section sixty-eight hundred ten of the education law and for which payment is authorized pursuant to paragraph (g) of subdivision two of section three hundred sixty-five-a of this title, the department shall pay a pharmacy dispensing fee for each such prescription drug dispensed, which dispensing fee shall not be less than the following amounts:

- (i) for prescription drugs categorized as generic by the prescription drug pricing service used by the department, four dollars and fifty cents per prescription; and
- (ii) for prescription drugs categorized as brand-name prescription drugs by the prescription drug pricing service used by the department, three dollars and fifty cents per prescription.

(Social Services Law § 367-a [9] [amended eff. April 2006, L.2006, c. 109, pt. C, § 32]). Prior to 2003, the EAC was defined as AWP minus ten (10) percent (VC § 114; SSL former § 367-a (9) (b) (ii) [prior to May 15, 2003]; see generally *Pharmaceutical Soc. of the State of New York, Incorporated v New York State Dept. of Soc. Servs.*, 50 F3d 1168 [2d Cir 1995]; *Still's Pharmacy, Inc. v Cuomo*, 981 F2d 632, 637 [2d Cir 1992]). In 2004, New York amended its reimbursement scheme to include an alternate formula for multiple source generic drugs, of “maximum acquisition cost” (MAC), which may be set by the commissioner of health “until such time as a specific federal upper payment limit has been established for such drug. The department shall use a similar methodology in establishing such an interim price as that utilized by the Centers for Medicare and Medicaid services in establishing the federal upper payment limit” (SSL § 367-a [9] [e]). As of 2009, the formula will change again (see *id.* [9] [eff. March 31, 2009] [dispensing fees increase but EAC will be AWP minus ten percent or pharmacy's usual and customary price to the general public]).

source generic drugs are reimbursed at the lower of average wholesale price (AWP) less 20 percent or the usual and customary charge to the public or the maximum acquisition cost, if one has been established by the State (*id.*).⁴

The available doses and packaging of each prescription drug on the market are assigned a National Drug Code ("NDC code") or formulary code, which is published by the United States Food and Drug Administration ("FDA"). According to Plaintiff, a separate AWP is published for each drug with an NDC code. There are an estimated 65,000 drug products in the United States market (*see* VC ¶¶ 108-109).

Joint Defendants assert, however, that "there is no statutory or regulatory definition of 'average wholesale price' and there is no statutory requirement that the State use any particular 'prescription drug pricing service' to obtain pricing information" (Jt. Defendant's Memo at 6). In other words, the marketplace is supposed to set AWP, based upon reporting by Defendants in conjunction with nonparty publishing services.

According to the Verified Complaint (VC), nonparty publishing services such as the "American Druggist First Data Bank Annual Directory of Pharmaceuticals", the "Essential Directory of Pharmaceuticals" (the "Blue Book"), the "Medi-Span's Master Drug Database" and Thomson's "RedBook", all publish and report AWP in print and electronic form "based on wholesale price information supplied by the [D]efendants" (VC ¶ 111).⁵

⁴ The parties fail to detail whether usual and customary charge to the public is generally higher than AWP minus 13.25 % or 20%, respectively.

⁵ For example, a study by the HCFA (forerunner of the CMS) of the cost of chemotherapy drugs administered by physicians, included information obtained by discussions with representatives of the Red Book "to determine the usefulness of the national AWP as a measure of the EAC for drugs to physicians." (Quinn

According to Plaintiff, each of the Defendants has intentionally submitted wholesale pricing information to the publishers that Defendants knew were false and misleading (*see* VC ¶ 116). In fact, Plaintiff alleges that reported AWP are completely fabricated, in that no one in the chain of distribution pays AWP for the drugs at issue (*id.* ¶ 120). Plaintiff asserts that “[t]he only purpose to inflate an AWP is to generate a marketable spread” (*id.*) Among the reasons that AWP are false is that they have not accounted for routine discounts such as prompt pay discounts, free samples, chargebacks, and other inducements provided to pharmacists which render the actual price paid by pharmacists less – sometimes far less – than the AWP (*see* VC ¶¶121-122). Thus, the “inflated AWP created a large discrepancy between the actual price paid by * * * pharmacists to acquire pharmaceuticals, and the reimbursements paid to these entities by Medicaid,” which discrepancy, according to Plaintiff, “was concocted by the defendants and coined ‘the spread’” (*see* VC ¶¶8-9). Defendants allegedly marketed this spread to pharmacists, specifically with respect to generic drugs or types of drugs for which there were similar alternatives; the greater the spread to the pharmacy, the more money the pharmacy would make selling a particular Defendant’s drug, and the more of that drug the Defendant would sell – thereby also increasing its profit and market share (*see* VC ¶¶10-15). “Based upon information and belief”, each Defendant was involved in the practice (VC ¶ 17).

Affirm., Exhibit L [DHHS, OIG “Physicians’ Costs for Chemotherapy Drugs, Nov. 1992, Appendix II]). The report stated in part: “The Red Book officials explained that the primary source of information for the published AWP is the drug manufacturers. They corroborate this with information from wholesalers and claims processors. Since these sources may provide different AWP for the exact same drug, the Red Book uses algorithms to weight the information based on general information about distribution channels and relative sale volumes for the various sources” (*id.* [emphasis supplied]).

According to a 2003 report from the United States Department of Health and Human Services Office of Inspector General (hereinafter HHS/OIG), entitled *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*:

The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit

(68 FR 23731, 23736 [May 2003]).

With regard to damages, Plaintiff alleges that the Defendants' allegedly fraudulent conduct was the sole cause of the Medicaid cost increases in Erie County (*see* VC ¶ 22). As noted, although the State is responsible for reimbursing pharmacists for prescriptions filled for persons qualified for Medicaid, Erie County as a local social service district must pay twenty-five percent (25%) of the costs for covered drugs for its residents (*see* VC ¶ 3, citing Social Services Law [SSL] §§367-a, 368-a, 368-b; *see also supra*, n.1).

B. PROCEDURAL HISTORY

The Verified Complaint was filed on March 8, 2005 (Pennock Affirm. ¶ 4 & Exhibit A). Plaintiff alleges causes of action for, one, fraud; two, a violation of SSL § 366-b, a criminal statute allegedly giving rise to a private cause of action; three, a violation of SSL § 145-b, for obtaining public funds by false statements; four, a violation of General Business Law § 349, which bars deceptive acts and unfair trade practices in any trade or business; five, unjust enrichment; and six, fraudulent concealment.

On April 15, 2005, certain Defendants removed the case to the United States District Court for the Western District of New York, and thereupon moved to stay all proceedings pending the transfer of the case to the Multi-District Litigation, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456 (D Mass), presently pending before the Hon. Patti Saris (hereinafter the AWP MDL). By order dated August 16, 2005, the Judicial Panel on Multi-District Litigation transferred the case to the MDL (*see* Plaintiff's Memo of Law at 5). As noted, Judge Saris remanded the action to this Court on January 9, 2006, based upon a lack of diversity jurisdiction. On February 28, 2006, this Court denied without prejudice Defendants' application to sever the claims against the non-diverse Defendants.

Thereafter, Defendants served the instant motions to dismiss.

C. DISCUSSION

1. Motion to Dismiss: Standard

A motion to dismiss pursuant to CPLR 3211(a) (7) "must be denied if from the pleadings' four corners factual allegations are discerned which taken together manifest any cause of action cognizable at law" (*511 West 232nd Owners Corp. v Jennifer Realty Co.*, 98 NY2d 144, 152 [2002] [internal quotation marks omitted]). Reading the Complaint in a liberal fashion, the Court must also "accept as true the facts as alleged in the complaint and submissions in opposition to the motion, accord [Plaintiff] the benefit of every possible favorable inference, and determine only whether the facts as alleged fit within any cognizable legal theory" (*Sokoloff v Harriman Estates Development Corp.*, 96 NY2d 409, 414 [2001]). The question is whether the Plaintiff has a cause of action, not whether it has stated one (*see Leon v Martinez*, 84 NY2d 83, 88 [1994], citing *Guggenheimer v Ginzburg*, 43 NY2d 268, 275 [1977]).

2. Joint Motion to Dismiss All Causes of Action

a. Fraud

i. Pleading with Sufficient Detail

Pleading of a fraud cause of action requires the following elements: “a misrepresentation * * * of fact which was false and known to be false by defendant, made for the purpose of inducing the other party to rely upon it, justifiable reliance of the other party on the misrepresentation or material omission, and injury” (NY Pattern Jury Instructions [2006] section 3:20, Comment; *see generally Brenner v American Cyanamid Co.*, 288 AD2d 869, 870 [4th Dept 2001]).

Defendants contend that the fraud cause of action must be dismissed because it does not set forth the “circumstances constituting the wrong”, in other words the “particular pricing representations alleged to be false, the identities of the speakers and recipients, the specifics of reliance by the County, and the circumstances of injury to the County” (Jt. Defendants’ Memo of Law at 23). Joint Defendants assert that the Verified Complaint fails to identify either the particular drugs about which misrepresentations allegedly were made or the specific prices on which the State and County allegedly relied, and, in general, that the Verified Complaint contains “generalized” pleading that is insufficient to support such a fraud claim (*id.* at 23, citing *In re AWP MDL*, 263 FSupp 2d 172, 194 [D. Mass May 13, 2003] [requiring more specific pleading from association plaintiffs, in class action]).

The so-called “Erie-Only Defendants” assert that the purpose of the “particularity requirement” of CPLR 3016 (b) is in part to prevent the assertion of claims that are based solely

upon "rumors of widespread fraud in a particular industry" (Erie-Only Defendants' Memo at 3, citing *Cooper v Blue Cross and Blue Shield of Florida*, 19 F3d 562, 566-567 [11th Cir 1994]).

In response, Plaintiff contends initially that, with respect to the sufficiency of the pleading, to the extent the information is not in the exclusive possession and control of Defendants, Plaintiff has pleaded the factual bases underlying the necessary elements of its causes of action in fraud to adequately satisfy the CPLR (*see* Plaintiff's Memo of Law at 9-19). Specifically, Plaintiff asserts that it has pleaded its common law fraud claims with sufficient detail to satisfy both the "notice" requirement of CPLR 3013 and the "detail" requirement of CPLR 3016 (b).

Under CPLR 3013, labeled "Particularity of Statements Generally",

Statements in a pleading shall be sufficiently particular to give the court and parties notice of the transactions, occurrences, or series of transactions or occurrences, intended to be proved and the material elements of each cause of action or defense

(CPLR 3013). Under CPLR 3016(b), relating specifically to the pleading of fraud causes of action:

Where a cause of action * * * is based upon misrepresentation [or] fraud, * * *, the circumstances constituting the wrong shall be stated in detail

(CPLR 3016).

The standard for pleading fraud under the Federal Rules of Civil Procedure is Rule 9(b):

(b) Fraud, Mistake * * *. In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity

(Federal Rules of Civil Procedure 9[b]). Federal pleading standards under Federal Rules of Civil Procedure 9 (b) are more strict than under the CPLR.

According to the United States District Court of the Northern District of Illinois, under Rule 9(b), "the Complaint must state 'the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated' [citations omitted]. Rule 9(b), however, must be read in conjunction with Rule 8, which requires a short and concise pleading" (*Fujisawa Pharmaceutical Co., Ltd. v. Kapoor*, 814 F Supp 720, 725 [ND Ill 1993] [read together, Rules require pleading of time, place and contents of fraud, but the complainant need not plead evidence]).

With respect to CPLR 3016 (b), Professor Siegel has stated:

This provision is not popular with the judges. It has been salutarily subordinated to CPLR 3013 by *Foley v D'Agostino*, 21 AD2d 60 (1st Dep't 1964), which said that even in instances involving fraud or breach of trust, which fall under CPLR 3016(b), the pleading's sufficiency still "primarily depends upon compliance with CPLR 3013's basic requirements". In other words, what's good enough for CPLR 3013 is good enough for CPLR 3016(b). It will usually be found, in fact, that noncompliance with 3016(b) also constitutes noncompliance with CPLR 3013, making 3016(b) superfluous * * *

(Siegel, Practice Commentaries, McKinneys Cons Laws of NY, CPLR 3016:3; *see also Jered Constructing Corp. v. New York City Transit Authority*, 22 NY2d 187, 194 [1968] ["It is almost impossible to state in detail the circumstances constituting a fraud where those circumstances are peculiarly within the knowledge" of the opposing party]). "[CPLR 3016 (b)] requires only that the misconduct complained of be set forth in sufficient detail to clearly inform a defendant with respect to the incidents complained of and is not to be interpreted so strictly as to prevent an otherwise valid cause of action in situations where it may be impossible to state in detail the circumstances constituting a fraud" (*Lanzi v Brooks*, 43 NY2d 778, 780 [1977] [internal citation omitted]).

Most importantly for this case, Professor Siegel notes that the presence of the different standard under Federal Rules of Civil Procedure 9(b) "is warranted because there is no bill of particulars in federal civil practice to supply the detail" (Siegel, Practice Commentaries, McKinneys Cons Laws of NY, CPLR 3016:3).

Here, citing cases relying upon Federal Rules of Civil Procedure 9(b), Defendants assert repeatedly that Plaintiff has failed to plead fraud with "particularity". Such reliance is not appropriate, because the State standards do not require Plaintiff here to plead the degree of evidence that Defendants claim they need to understand the complaints against them. Not that the ninety-six (96) page Verified Complaint is devoid of details. The Court notes that, in addition to the general competitive scheme described by the Verified Complaint, specific allegations include that AWP's were published in various third-party publications; with respect to each of sixty-eight (68) different Defendants out of seventy-seven (77), the Verified Complaint cites at least one specific drug prescribed to Medicaid recipients in 2002 in Erie County, and the estimated percentage difference between the actual wholesale price of a popular dosage of that drug and the published AWP of that drug (*see* VC ¶¶162-484). For fifty-five (55) of those Defendants, the Verified Complaint also alleges the dollar amount estimated to have been overpaid by Plaintiff for that dosage of that drug (*see id.*).

The Verified Complaint does not give each instance of allegedly fraudulent publication, over the period from 1992 through the filing of the Complaint; it does not indicate how Plaintiff estimated the amount by which the AWP's were allegedly overstated, nor how each Defendant allegedly created the "spread" between the actual cost to pharmacies and the published AWP. As it is, however, the Verified Complaint is already excessively long. Keeping in mind the

procedural context of a motion to dismiss, the Court notes that Plaintiff's allegations are not simply that AWP's did not reflect the prices at which Defendants sold their goods to a willing intermediary. Rather, it was Defendants' alleged actions -- in giving away samples, cash discounts, rebates, coupons, goods in kind, free or reduced price services or other price concessions (*see* VC ¶ 115), with the effect of decreasing the net cost of the drugs to pharmacies, that rendered the AWP's false. These actions (if taken) are necessarily known to Defendants and not to Plaintiff. Thus, the Court determines that CPLR 3016 (b) does not require more than Plaintiff has alleged here.

ii. Reliance by Plaintiff County of Erie on AWP Misrepresentations

Joint Defendants contend that Plaintiff may not base a cause of action in fraud on alleged reliance by a third party -- here, the State -- as it is the State, under New York's Medicaid program, that determines the amount providers are reimbursed for pharmaceuticals (*see* *Jt. Defendants' Memo of Law* at 10). Thus, Defendants contend, whatever Plaintiff understood AWP to represent had no impact upon its actions or its expenditures, as it simply pays its portion of State Medicaid expenditures (*see id.*, citing *McMahon v Novello*, 192 F Supp 2d 54, 67 [WDNY 2001]).

Joint Defendants rely heavily upon a decision by Judge Saris in the AWP MDL (*see In re AWP MDL*, No. 1456, *County of Suffolk v Abbott Laboratories* [hereinafter *Suffolk I*], 339 FSupp2d 165, 180 [D. Mass Sept. 30, 2004]). In that case, the County of Suffolk had sued many of the same Defendants based upon alleged overcharges due to false AWPS for self-administered pharmaceuticals prescribed under Medicaid (*see id.* at 173). That case originally included a number of federal claims, as well as six claims under State law, including common-law fraud. In

the decision cited, Judge Saris granted the defendants' motion to dismiss the claim for common law fraud on the ground that the County was merely a third-party to the alleged misrepresentations (*see id.* at 180). Judge Saris relied on *Cement & Concrete Workers Dist. Council Welfare Fund v Lollo* (148 F3d 194 [2d Cir 1998]) in which the Second Circuit interpreted New York law to hold that "a plaintiff does not establish the reliance element of fraud for purposes of * * * New York law by showing only that a third party relied on a defendant's false statements" (*id.* at 196).

That statement, however, is not correct. As noted by Plaintiff, there are two lines of cases under New York law concerning third-party reliance as a basis for fraud. The oldest line of cases begins with *Eaton, Cole & Burnham Co. v Avery* (83 NY 31, 33-34 [1880]), which held that the plaintiff, a seller of goods, could state a claim for fraud based upon its reliance upon false statements made to a third party, a mercantile agency, concerning the creditworthiness of defendant, upon which plaintiff relied in delivering goods on credit (*see id.* at 33-34). As noted by the United States District Court from the Southern District of New York in *N.B. Garments (PVT.) Ltd. v Kids Internat'l Corp.* (2004 WL 444555 [SDNY Mar. 10, 2004]):

By way of history, about a century after the *Eaton* line of cases, without any reference to binding authority from their parent court, lower New York state courts began to hold that common law fraud *was not* cognizable when based on the reliance of a third-party. *See Garelick v Carmel*, 141 AD2d 501, 502 [2d Dept 1988]; *Orlin v Torf*, 513 NYS2d 870, 872 [3rd Dept 1987]; *Escoett & Co. v Alexander & Alexander, Inc.*, 31 AD2d 791 [1st Dept 1969] * * * (hereinafter referred to collectively as "the *Garelick* line"). Then, the snowball effect began to take further hold, and courts in this district cited exclusively to the *Garelick* line (without reference to the *Eaton* line) to conclude that in New York "a claim of fraud will not lie when premised on reliance of a third-party." *See e.g. Shaw v Rolex Watch, U.S.A., Inc.*, 673 FSupp. 674, 682 (SDNY 1987). And, to make matters worse, the Second Circuit followed this conclusion, with reliance on the *Garelick* line (still, without citation to or discussion of the *Eaton* line)

(*N.B. Garments (PVT), Ltd. v Kids Internat'l. Corp.*, 2004 WL 444555, *3 [SDNY 2004] [emphasis in original]), citing *Cement & Concrete Workers*, 148 F3d at 196-197; *Kelly v L.L. Cool J.*, 145 FRD 32, 39 n.8 [SDNY1992], *aff'd* 23 F3d 398 [2d Cir1994]).

Eaton, though old, contains a cogent discussion of the issue:

The counsel for the appellant is undoubtedly right in his general proposition that a false representation made to one person cannot give a right of action to another to whom it may be communicated, and who acts in reliance upon its truth. If A. casually or from vanity makes a false or exaggerated statement of his pecuniary means to B. or even if he does so with intent to deceive and defraud B. and B. communicates the statement to C. who acts upon it, A. cannot be held as for a false representation to C. *But if A. makes the statement to B. for the purpose of being communicated to C. or intending that it shall reach and influence him, he can be so held*

(*Eaton, Cole & Burnham Co. v Avery*, 83 NY at 34-35 [emphasis supplied]).

This Court is constrained to follow the Court of Appeals precedent in the *Eaton* line of cases, and declines to dismiss the fraud cause of action on this basis.

iii. Issue of Reasonable Reliance

Joint Defendants contend that, even if New York law permitted a recovery for fraud based on reliance upon a statement made to a third-party, such reliance could not as a matter of law have been reasonable, due to the “vast, decades-old public record”, as a result of which the State has “expressly understood for years that AWP is a pricing benchmark that is not reflective of a provider’s acquisition cost” (*see* Jt. Defendants Memo of Law at 12; *see generally id.* at 11-16). Joint Defendants invite the Court to take judicial notice of government and other publicly

available documents and “read them into the complaint” (*see id.* at 12 n. 9, citing *St. Regis Tribe of Mohawk Indians v State*, 5 NY2d 24, 36 [1958]).⁶

With respect to the reasonableness of reliance, the Court has reviewed the many government documents cited by Joint Defendants, along with others cited therein and various articles in the literature. Keeping in mind the procedural context of a motion to dismiss, the Court notes again that Plaintiff’s allegations are not simply that AWP’s did not reflect the prices at which Defendants sold their goods to a willing intermediary. Rather, it was Defendants’ alleged actions – in giving away samples, cash discounts, rebates, coupons, goods in kind, free or reduced price services or other price concessions (*see* VC ¶ 115), with the effect of decreasing the net cost of the drugs to pharmacies, that rendered the AWP’s false. There is nothing in the literature that establishes that such actions – the nature of which apparently varied widely over time – were or are known to Plaintiff or to the State.

In addition, the literature documents a steadily increasing spread between the actual cost of drugs to pharmacies for ultimate dispensing to Medicaid beneficiaries, and the reported AWP’s. In August 1989, the HCFA (now CMS) “issued a revision to the State Medicaid Manual pointing out the preponderance of evidence demonstrating that AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent” (*OIG Report Concerning*

⁶ Joint Defendants also note that, under the New York SSL, “[e]very manufacturer or wholesaler of drugs * * * shall, upon request of the [Department of Health] for any information pertaining to wholesale prices charged to pharmacists for any drugs available under [Medicaid], make the requested information available to the department on a monthly basis, or such other periodic basis as the department shall request” (SSL § 367-a [7] [a]).

Medicaid and Medicare Reimbursement for Drugs [Oct. 03, 1989], at Quinn Affirm Exhibit G at

1).

The *Manual* issuance provides that, absent valid documentation to the contrary, it will not be acceptable under Medicaid for a state to make reimbursements using AWP without a significant discount.

We fully concur with this pronouncement that the preponderance of evidence shows that AWP is heavily discounted (sic). During 1984, we issued a report entitled "Changes to the Medicaid Prescription Drug Program Could Save Millions" * * * which concluded that, on average, pharmacies buy drugs for 15.9 percent below AWP.

(*id.*).

Nonetheless, it is alleged that, as the State adjusted its reimbursements to take into account the inflation of AWP's, Defendants inflated the AWPS more, to maintain a "spread". For example, according to the Verified Complaint, a number of AWP's for drugs prescribed to Medicaid recipients in Erie County were between 20 and 25 percent over the actual cost to the prescribing pharmacies (*see e.g.* VC ¶ 165, 176, 188, 196 [40 %], 203); an HHS/OIG report estimated that pharmacies' actual acquisition costs for generic drugs was at the low end 65 percent below the reported AWP's across the board in 1999 (VC ¶136); a September 2000 General Accounting Office Report determined that actual retail prices for Defendant Boehringer Ingelheim's Albuterol and Ipratropium were 85 percent and 75 percent less than their AWP's (VC § 133). (As noted, in New York, generic drugs without a FUL or a MAC, are currently reimbursed at AWP less 20 % [*see* SSL § 367-a (9) (b)(ii)] [amended 2006]).

In 2003, HHS/OIG reiterated that "pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes" (*OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 FR 23731, 23734

[May 5, 2003]; *see also In re AWP MDL*, 263 FSupp2d 172, 180 n.6 [D Mass. May 13, 2003]).

Thus, the record indicates that, short of setting a specific price for the drugs, the State was forced to rely on the most recent estimates of overcharges. Whether such reliance was reasonable under the circumstances cannot be determined as a matter of law (*see In re AWP MDL*, No. 1456, *Suffolk I*, 339 FSupp2d at 182 [whether existence of the AWP spread was common knowledge, eviscerating the harm under a General Business Law § 349 claim was a factual issue not then capable of resolution]).

Thus, the Joint Defendants' Motion insofar as it seeks to dismiss the fraud cause of action is dismissed.

b. Fraudulent Concealment

With respect to the sixth cause of action for fraudulent concealment, Plaintiff must allege the six required elements of a fraud cause of action, along with a duty on Defendants' part to disclose material information (*see* Jt. Defendants Memo of Law at 21-22, citing *E. B. Liberation Publications Inc.*, 7 AD3d 566, 567 [2d Dept 2004]; *see also Mars v Diocese of Rochester*, 6 AD3d 1120, 1121 [4th Dept 2004], *lv denied* 3 NY3d 608 [2004]). Although the Court determines that Plaintiff has stated a cause of action for fraud, the fraudulent concealment cause of action must be dismissed.

Although a fraudulent concealment cause of action may be based upon a mere failure to disclose a material fact,

[t]he law requires disclosure to be made only when there is a duty to make it, and this duty is not raised by the mere circumstance that the undisclosed fact is material, and is known to the one party, and not to the other, or by the additional circumstance that the party to whom it is known, knows that the other party is acting in ignorance of it. * * * It is not fraud for one party to say nothing on the

subject where no confidential or fiduciary relation exists and where no false statement or acts to mislead the other are made

(*Amend v Hurley*, 293 NY 587, 596 [1944] [internal quotation marks omitted]).

The existence of a fiduciary duty gives rise to a slew of duties, including a duty not “to injure or act contrary to the interests of the person to whom the duty of loyalty is owed”

(*Mandelblatt v Devon Stores*, 132 AD2d 162, 168 [2d Dept 1987]). As stated by Justice Cardozo, “a fiduciary has a duty to act with the utmost honesty and loyalty * * *. A trustee is held to something stricter than the morals of the market place. Not honesty alone, but the punctilio of an honor the most sensitive, is then the standard of behavior” (*Meinhard v Salmon*, 249 NY 458, 464 [1928]). As a matter of law, Plaintiff has failed to allege any basis for such a duty to exist in this situation by statute, rule, common law or any other basis. The sixth cause of action is dismissed.

c. Social Services Law § 145-b

New York Social Services Law section 145-b provides in pertinent part:

(1)(a) It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, *on behalf of himself or others*, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to [the Medicaid statutes].

(b) For purposes of this section, “statement or representation” includes, but is not limited to: a claim for payment made to the state, [or] a political subdivision of the state * * *; an acknowledgment, certification, claim, ratification, *or report of data which serves as the basis for a claim or a rate of payment* * * *.

(c) For purposes of this section, * * * [a] corporation has attempted to obtain or has obtained public funds when any portion of the funds from which payment was attempted or obtained are public funds, *or any public funds are used to reimburse or make prospective payment to an entity from which payment was attempted or obtained*

(Social Services Law § 145-b [1] [emphasis added]).⁷

In the AWP MDL, Judge Saris considered whether Suffolk County had a cause of action against numerous pharmaceutical companies under section 145-b (*see Suffolk I*, 339 FSupp 2d 165 [D Mass Sept. 30, 2004]). The Judge denied the defendants' motion to dismiss this cause of action, stating:

The language of [section 145-b] encompasses the AWP scheme alleged by [the County], that is, that a pharmaceutical company made a fraudulent statement regarding AWP in order to get a higher reimbursement rate for providers who purchase its drugs. The scheme fits into 1(a) and (b), because Defendants attempted to obtain, "on behalf of" providers, payment from public funds through means of reporting of false data (the AWPs) that served as the basis for the claims of the providers. Alternatively, under 1(c), Defendants arguably obtained public funds when public funds were used to reimburse providers, from whom Defendants obtained payment

(*Suffolk I*, 339 FSupp2d at 179).

As in *Suffolk I*, Defendants here rely upon a decision from Supreme Court, Albany County, *New York v Pharmacia Corp.*, (Index Nos. 905-04, 905-03, 1150-03 [Sup Ct Albany County June 1, 2004] [Benza, J.]) (*see* Jt. Defendants' Memo, Exhibit A, [hereinafter *Pharmacia*], Slip Op. at 10). In that case, Justice Benza determined that the State had failed to state a cause of action under section 145-b against various pharmaceutical companies based upon overstated AWPs, because "there [were] no allegation[s] that defendants received any public funds as a result of their actions" (*Pharmacia*, Slip Op. at 10). Defendants assert that

⁷ SSL § 145-b was substantially amended by L. 2006, ch. 442, § 7, effective July 26, 2006. Subdivision (2) of the statute was amended and a fifth subdivision added. Because the parties have not briefed the changes, the Court declines to address them here.

Pharmacia has superior precedential value over Judge Saris's decision, on this issue of New York law (*see* Jt. Defendants' Memo at 18 n. 19).

This Court is not bound by Supreme Court's interpretation of the statute. Plaintiff alleges that "defendants made fraudulent AWP statements 'on behalf of' intermediaries to induce them to sell more of defendants' drugs, thereby gaining a greater portion of the market share" (Plaintiff's Memo at 37). Subdivision c of the statute states that "a corporation has attempted to obtain or has obtained [public] funds when *** any public funds are used to reimburse * * * an entity from which payment was * * * obtained" (SSL § 145-b [1] [c]), which would cover the situation of pharmaceutical companies obtaining payment from pharmacies, that are then reimbursed through public funds.

Defendants assert that the legislative history of the statute indicates the legislative intent to discourage the filing of fraudulent or unsubstantiated Medicaid claims; but that the stating of claims against pharmaceutical manufacturers "goes well beyond the scope of this legislative intent" (*see* Jt. Defendants' Memo of Law at 18 n.18). As is evident from the 1975 legislative history submitted by Defendants, however, the statute was also aimed at "providers of * * * supplies" that engage in fraudulent conduct with regard to the Medicaid program (Quinn Affid. Exhibit O, at 1).

Thus, the Court determines that Plaintiff has stated a cause of action under SSL § 145-b.

d. Social Services Law § 366-b

Joint Defendants contend that it would be contrary to the legislative intent of Social Services Law § 366-b and related statutes to imply a private right of action in favor of Plaintiff

County from that criminal statute (*see* Jt. Defendants' Memo at 16-17; Reply Memo at 4-5). The Court agrees.

Section 366-b provides in pertinent part:

* * *

2. Any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing * * * merchandise, or knowingly submits false information for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing * * * merchandise, or knowingly submits false information for the purpose of obtaining authorization for furnishing * * * merchandise under this title, *shall be guilty of a class A misdemeanor*, unless such act constitutes a violation of a provision of the penal law of the state of New York, in which case he shall be punished in accordance with the penalties fixed by such law.

(Social Services Law § 366-b [added L.1970, c. 306, § 1] [emphasis supplied]).

Under *Sheehy v Big Flats Community Day, Inc.* (73 NY2d 629 [1989]), a case relied upon by both Joint Defendants and Plaintiff, a court must consider the existence of three factors in order to imply a private right of action from a criminal statute:

(1) whether the plaintiff is one of the class for whose particular benefit the statute was enacted; (2) whether recognition of a private right of action would promote the legislative purpose; and (3) whether creation of such a right would be consistent with the legislative scheme

(*Sheehy v Big Flats Community Day, Inc.*, 73 NY2d at 633).

The Court determines that to imply a private right of action under section 366-b would be inconsistent with the evident legislative scheme. In 1975, the State Legislature added SSL § 145-b (discussed *supra*). In a memorandum, the Executive Department stated:

This bill will provide a significant financial deterrent to the practice of overstating or falsely stating figures in cost or rate setting forms used for Medicaid reimbursement and to the practice of overstating or falsely stating claims for services rendered, either by nursing homes, hospitals, physicians or other Medicaid providers.

*This bill provides a necessary complement to a whole range of existing criminal statutes. * ***

To supplement these criminal offenses with a strong financial deterrent in the form of treble damages is a necessary step in regulating abuse in the Medicaid field. Traditionally, treble damages statutes are drafted to create a private right of action for an injured party to recover three times the amount of his actual damages. However, we have found no legal barrier to creating the same right of action for the State. Particularly in this matter of great public concern the State should be in the position to create a significant financial, as well as criminal, deterrent

(1975 NY Session Laws c. 659, Memo of State Executive Dept., at 1686-1687 [emphasis supplied]). When enacted, however, the law gave the local social service districts, as well as the State, the right to sue (*see* L. 1975, c. 659, § 1). Thus, the legislative scheme clearly envisioned that section 145-b would provide a civil right of action, as a complement to the existing criminal statutes, including section 366-b.⁸ In the Court's view, to imply a private right of action under section 366-b in addition to section 145-b, would be superfluous in this situation.

The Court grants the motion to dismiss the cause of action under SSL § 366-b as against all Defendants.

e. General Business Law § 349

Joint Defendants contend that Court of Appeals' precedent bars the County of Erie from recovering "derivatively" under General Business Law (GBL) § 349, and that Plaintiff otherwise failed to assert such a cause of action, because the extensive public record belies any allegation that Defendants' conduct was misleading, there is no allegation that Defendants made any representations to consumers, and there can be no evidence of proximate cause (*see* It Defendants' Memo at 18-19).

⁸ L. 2006, ch. 242, § 9 adds a new article 177 to the Penal Law entitled Health Care Fraud, including crimes ranging from B felonies to class A misdemeanors.

To state a cause of action under GBL § 349, Plaintiff must allege: “first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act” (*Stutman v Chemical Bank*, 95 NY2d 24, 29 [2000]). “[W]hile the statute does not require proof of justifiable reliance, a plaintiff seeking compensatory damages must show that the defendant engaged in a material deceptive act or practice that caused actual, although not necessarily pecuniary, harm” (*Oswego Laborers’ Local 214 Pension Fund v Marine Midland Bank, N.A.*, 85 NY2d 20, 26 [1995]).

The issue of the viability of a GBL § 349 claim arose in the NY MDL. Judge Saris stated in *Suffolk I*:

Defendants argue first that the reporting of AWP’s was not “consumer oriented” within the meaning of [GBL] Section 349. The Court disagrees. The Defendants made the representations (the AWP’s) understanding that consumers would be making payments based on those representations. While government agencies also used the AWP’s as the basis for reimbursement, this does not change the fact that the Defendants’ conduct affected the public interest through harm to consumers. Additionally, harm to public agencies impacts the public interest. *See [Securitron [Magnalock Corp. v Schnabolk*, 65 F.3d 256, 264 [2d Cir 1995] (harm to public interest established by “interference with [public safety agency’s] decisionmaking process” and distraction of agency by false reports).

(*In re AWP MDL, Suffolk I*, 339 F Supp2d 165, 182 [(D Mass Sept. 30, 2004)]).

With respect to Joint Defendants’ contention that there could be no harm under GBL §349 because the existence of the AWP spread was common knowledge, the Court stated “[t]his presents a factual issue inappropriate for resolution at this stage” (*Suffolk I*, 339 FSupp 2d at 183). Finally, with respect to the argument that the County of Suffolk could not recover because its “injury” was derivative of that of the State, Judge Saris held that the Court might “revisit the

issue” after the New York Court of Appeals answered a question of indirect standing under section 349 certified to it by the United States Court of Appeals for the Second Circuit (*id.* at 183-184).

The New York Court of Appeals has since done so (*see Blue Cross & Blue Shield of N.J. Inc v Philip Morris USA*, 3 NY3d 200 [2004]). The Court of Appeals held:

* * * [A] third-party payer has no standing to bring an action under General Business Law § 349 because its claims are too remote * * * . In so holding, we do not leave plaintiff without remedy. As an insurer, Empire’s traditional common-law remedy to recover excess amounts paid on behalf of an insured, arising from the misconduct of a third party, is an action in equitable subrogation

(*id.* at 208 [emphasis supplied]).

Plaintiff distinguishes *Blue Cross*, by asserting that it, as a County government required to pay 25 percent of Medicaid costs, is the injured party (*see* Plaintiff’s Memo at 40). Further, Plaintiff notes that several public welfare statutes explicitly empower counties to file suits for the cost of medical treatment in certain situations (*see* SSL §§145-b, 369). Further, New York courts have held that, under the prior Medicaid system, where the local social services districts paid providers directly, that the State could nonetheless sue providers directly to recover benefits fraudulently obtained, without joining the local district (*see e.g State v Estate of Frankel*, 65 Ad2d 788, 788-789 [2d Dept 1978]). Therefore, Plaintiff asserts, “the party need not be the payer to have enforcement power where the right to recover is explicitly provided by statute” (Plaintiff’s Memo at 41). Further, Plaintiff notes that SSL §145-b grants counties as well as the State the right to recover treble damages for false statements made to obtain payments from public funds. The existence of such a cause of action, however, is not a good argument for

permitting recovery under GBL §349, which is also a treble-damages statute, where the Court of Appeals explicitly held that no “third-party payer” has standing under the statute.

The Court agrees that Plaintiff (and the State) are the alleged targets of the AWP misrepresentations and also are directly injured parties – whereas in the case of cigarette smoking, the smoker him- or herself was the most directly affected by misrepresentations about the dangers of smoking (*see Blue Cross*, 3 NY3d at 207). However, it is also true that the County here is as remote a party as the private insurer in *Blue Cross*. It is, in effect, an insurer of the poorest citizens.

Although it is a difficult question, the Court determines that it is constrained by *Blue Cross* to find that Plaintiff has failed to state a cause of action under GBL §349, and Joint Defendants’ motions to dismiss the fourth cause of action are granted.

f. Unjust Enrichment

Joint Defendants contend that the unjust enrichment claims fail because Defendants are not enriched by the alleged spread between AWP’s and the actual costs of drugs to providers, and because there is no correlation between the damages that Plaintiff seeks for the alleged overpayments and the funds over which Plaintiff seeks to impose a constructive trust (*see* *Jt. Defendants Memo* at 19-22).

Under New York law, the doctrine concerning imposition of a constructive trust is much broader than as contended by Defendants (*see Simonds v Simonds*, 45 NY2d 233, 241 [1978] [(“a) constructive trust will be erected whenever necessary to satisfy the demands of justice”] [citation omitted]). With respect to the stating of a claim for unjust enrichment, “[t]he essential inquiry * * * is whether it is against equity and good conscience to permit the Defendant to

retain what is sought to be recovered" (*Paramount Film Dist. Corp v State*, 30 NY2d 415, 421 [1972], *cert denied* 94 SCt 57 [1973]).

Generally, courts will look to see if a benefit has been conferred on the defendant under mistake of fact or law, if the benefit still remains with the defendant, if there has been otherwise a change of position by the defendant, and whether the defendant's conduct was tortious or fraudulent (Restatement, Restitution, §§1, 142, esp. Comment B; *id.*, §155, including Comment B)

(*Paramount Film Dist. Corp.*, 30 NY2d at 421).

Plaintiff alleges that, as a direct and proximate result of the unlawful conduct described therein concerning fraudulent AWP's, Defendants have been and will continue to be unjustly enriched (VC ¶ 512).

Defendants have benefitted from their unlawful acts through the increased sale of drugs with the greatest spread. It would be inequitable for defendants to retain any of their ill-gotten gains earned as a result of the scheme alleged herein, which gains would not exist but for the overpayments made by the County Medicaid Program.

(VC ¶ 514). Thus, the allegations in the Verified Complaint are bare-bones, but sufficient.

In addition, Plaintiff has sufficiently alleged a benefit to Defendants (*see e.g. Cox v Microsoft Corp.*, 8 AD3d 39 [1st Dept 2004] [indirect benefit to wrongdoer sufficient]; *cf. Sperry v Crompton Corp.*, 26 AD3d 488, 500 [2d Dept 2006] [declining to follow *Cox*]). The case law cited by Joint Defendants is distinguishable (*see e.g. Citrin v CBS Inc.*, 29 AD2d 740 [1st Dept 1968] [Plaintiff sought a finder's fee in connection with sale of a business opportunity, where defendant was stranger to the transaction]; *Landcom Inc. v Galen -Lyons Joint Landfill Comm'n*, 259 AD2d 967 [4th Dept 1999] [nothing in record to support claim that defendants derived any benefit from plaintiff's services; no quasi-contract/quantum meruit claim]).

The motion to dismiss is denied with respect to the cause of action for unjust enrichment.

3. Separate Applications by Various Defendants

a. Separate Application by "Erie-Only Defendants"

Thirteen Defendants⁹ join together in a supplemental memorandum of law to highlight what they say are additional defects in Plaintiff's claims against them. The thirteen join together to differentiate them from the remaining Defendants, in that they (a) are not Defendants in any of the other AWP actions commenced by other New York counties and by the City of New York; (b) are not Defendants in any federal actions, and, with the exception of Eisai, (c) are not alleged to be the subject of any governmental investigation relating to AWP (*see* Erie-Only Defendants' Supplemental Memo at 2). Each of the thirteen Defendants filed supplemental papers, detailed below.

Alcon Laboratories, Inc. (Alcon) was initially named as a Defendant in the AWP MDL action involving New York City and many of the counties in New York (hereinafter the New York MDL Action) (*see* Haggerty Affirm. ¶ 4 & Exhibit A). However, on August 23, 2005, the plaintiffs in that action voluntarily dismissed all claims against Alcon without prejudice pursuant to Federal Rules of Civil Procedure 41 (a) (1) (*id.* Exhibit A). The only other pending related actions against Alcon are an action by the State of Alabama and one by the State of Mississippi (*see* Haggerty Affirm. ¶ 7). On that basis alone, in addition to the arguments made by the Erie-

⁹ The so-called "Erie-Only" Defendants are Alcon Laboratoies, Inc., Allergan, Inc., Andrx Pharmaceuticals, Inc., Berlex Laboratories, Inc., Biovail Corp., Biovail Pharmaceuticals, Inc., Eisai, Inc., Genentech, Inc., Genzyme Corp., Gilead Sciences, Inc., Novo Nordisk Pharmaceuticals Inc., Reliant Pharmaceuticals, and Takeda Pharmaceuticals North America, Inc. The contentions of Genentech are discussed in the following section, *infra*, section C(2).

Only Defendants' Memo of Law, Alcon submits that the instant claims against it should be dismissed.

Gilead Inc. was voluntarily dismissed from the New York MDL Action in August 2005, and is currently named only in the same two AWP-related actions as Alcon (*see* Sullivan Affirm., sworn to on March 10, 2006 & Exhibits A-C). Biovail Pharmaceuticals, Inc. is in the same situation, while Biovail Corp. has been named only in this litigation (*see* Mervis Affirm, dated March 10, 2006, ¶¶2-12).

Andrx Pharmaceuticals, Inc. (Andrx) is in the precise situation as Alcon: it was voluntarily dismissed from the New York MDL Action on August 23, 2005, and the only pending related lawsuits are the three brought by Plaintiff's counsel herein and suits by the States of Alabama and Mississippi (*see* Visco Affid. ¶3 & Exhibit A). Andrx's Boston counsel avers that, to his knowledge, Andrx has never been subject to any pricing-related investigation by any state or federal agency (*see* Visco Affid. Exhibit A [Matthews Affid.] ¶ 14). Novo Nordisk, Inc. (Novo) was named in the New York MDL Action but voluntarily dismissed from that action in August 2005, and allegedly has never been the subject of an AWP-related investigation (*see* Jones Affirm., dated March 10, 2006, ¶¶2-9).

Allergan, Inc. (Allergan) submits a separate affirmation of its counsel, asserting that, although it was originally named in the New York MDL action, a consolidated complaint filed in the action in June 2005 did not name Allergan, and it was voluntarily dismissed from the action on August 23, 2005 (*see* Jones Affirm., sworn to on March 10, 2006, ¶¶ 4-6).

Berlex Laboratories Inc. (Berlex), Genzyme, Inc., Reliant Pharmaceuticals, Inc. (Reliant), and Takeda Pharmaceuticals North America, Inc. (Takeda) were dismissed as Defendants from

the New York MDL Action as of August 23, 2005, and also dropped from the separate action by Nassau County (*see* Berman Affirms., sworn to on March 10, 2006, Exhibits A-C; Banas Affirm., sworn to on March 10, 2006, Exhibits A-C; Mooney Affirm, sworn to on March 10, 2006, Exhibits A-B).

Eisai, Inc. (Eisai) has been dismissed from the New York MDL Action (Banas Affirm. o/b/o Eisai, Exhibit A), but is the subject of an investigation by the United States Senate Finance Committee (*see* VC ¶ 404).

In response, Plaintiff asserts that the Erie-Only Defendants' contentions are directed at the merits of the claims, rather than the pleadings, and that the voluntary dismissal without prejudice of these Defendants by other Plaintiffs in other cases should have no bearing on this case (*see* Plaintiff's Memo at 47-48).

In their reply brief, the Erie-Only Defendants contend that they are not asserting that they should be dismissed simply because all of the other New York Counties have dropped claims against them; rather, they state that, as to them particularly, the Complaint fails to contain particularized allegations of misconduct adequate to allow them to "comprehend Plaintiff's theory or prepare a defense" (*see* Erie-Only Defendants' Reply Memo of Law & Exhibit A [*Wisconsin v Amgen, Inc.*, Cir Ct of Dane County Wisc, Apr. 3, 2006]). They state that it is the Plaintiff that has tried to make relevant the existence of other lawsuits, relying on them in the Complaint as a supposed basis for satisfying its obligation to plead fraud "with particularity" (*see* Reply Memo at 2).

In the Wisconsin trial court decision cited by these Defendants, the court applied a procedural rule mirroring Federal Rules of Civil Procedure 9 (b), requiring "particularized"

statements to allege fraud. The Wisconsin Court determined that the State was required to provide as much detail as it could, regarding each Defendant, "which of its drugs are involved and what (name, date) publication of AWP is false, and the actual price that should have been published" (*id.* Exhibit A at 13 [emphasis omitted]).

Here, Plaintiff alleges that actions secretly taken by Defendants herein created a spread between the published AWP (again, allegedly largely dependent upon numbers provided by Defendants to third-party publishers) and the actual cost to pharmacists: actions including providing samples, cash discounts, rebates, coupons, goods in kind, free or reduced price services or other price concessions (*see* VC ¶ 115). Because that information is peculiarly within Defendants' knowledge, Plaintiff herein is not required to provide it in the original Verified Complaint. As the Court has already ruled, the Verified Complaint states the fraud cause of action with sufficient detail against all Defendants. The separate application of the Erie-Only Defendants is denied.

b. Separate Application of Genentech, Inc.

Genentech, Inc. submits the affirmation of its attorney stating that the instant action is the only AWP action in which it is a named Defendant. It attaches to its affirmation an April, 8, 2005 memorandum decision by Judge Saris in *County of Suffolk v Abbott Labs*, a case consolidated with the AWP MDL (*see* Miller Affirm., Exhibit A [*In re AWP MDL, County of Suffolk v Abbott Laboratories*, 1:303-cv-10643 [Apr. 8, 2005] [hereinafter *Suffolk III*]). Discussion of that decision necessitates a limited delving into the history of the MDL.

That decision was a follow-up to a memorandum decision by Judge Saris in October 26, 2004 (*see In re AWP MDL, County of Suffolk v Abbott Laboratories*, 2004 WL 2387125, *1 [D

Mass. Oct. 26, 2004] [hereinafter *Suffolk II*]). At that time, twenty-two of the pharmaceutical company defendants had moved to dismiss Suffolk County's Amended Complaint. The October 2004 decision considered only State law claims: whether defendants had violated SSL §145-b and GBL §349, and had been unjustly enriched. The Court determined that it would defer ruling on whether to dismiss all AWP claims against thirteen defendants (the so-called "Suffolk 13"), until "in complying with the automatic disclosure requirements, Suffolk shall disclose * * * all documents upon which it relied in calculating the spreads, and provide, in writing, a more definite statement of its method of calculation [of the spreads between actual and AWP price]" pursuant to Federal Rules of Civil Procedure 12 (e) (*id.* at *2).

In response, the County of Suffolk submitted only an affidavit of an attorney who had calculated an alleged spread, based upon a single formula (retail prices being 1.27 times wholesale prices) (*see* Miller Affirm., Exhibit A, *Suffolk III*, Slip Op. at 2). In the April 2005 decision, the Court held that:

In light of the fact that there are approximately 60,000 prescription drugs in the United States, the use of the purported average difference between wholesale and retail, 1.27, to calculate the actual wholesale prices for each drug is inadequate.

(*id.*). The Court dismissed the remaining AWP claims against the "Suffolk 13", Amgen Inc., Johnson & Johnson, Warrick Pharmaceuticals Corp., and Wyeth, among others, for failure to comply with Rule 9(b) (*see id.* at 3).

Judge Saris' decision, however, was made after discovery had been conducted in the case (*see e.g. In re AWP MDL*, No. 1456, Case Management Orders No. 10 [March 25, 2004] [ordering document production of all documents relating to any drugs in Appendix A to the Amended Master Consolidated Complaint, in addition to documents produced to governmental

bodies concerning AWP matters]; Case Management Order issued Oct. 21, 2004 [re: First DataBank Inc., non-party publisher of drug pricing information, concerning depositions and documents produced by it]). In contrast, no discovery has occurred in this case. In addition, as noted the dismissal was under Rule 9 (b), inapplicable here. The separate application by Genentech is denied.

c. Separate Application by "Certain Defendants"

Certain Defendants¹⁰ submit a supplemental memorandum of law in addition to joining in the Joint Motion to Dismiss and supporting briefs, to bring the Court's attention to an alleged lack of supporting factual allegations concerning them (*see* Supplemental Memo of Law of Certain Defendants at 1). Specifically, these Certain Defendants assert (in addition to those assertions made by Joint Defendants) that "[o]ther than listing a single drug for each Defendant, Plaintiff fails to identify which of the Defendants' specific drugs are the subject of its claims, the allegedly fraudulent price for each drug and the identity of specific purchasers of those drugs", or any specific fraudulent AWP, and that Plaintiff fails to assert that any investigations were commenced against any of these Defendants, from which an allegation of fraud could be derived (*see id.* at 2).

Plaintiff responds that failure to detail any investigations, settlement or testimony implicating these Defendants in the fraudulent scheme is of no consequence where "the allegations of fraud are not directed at any one particular defendant; the complaint sets forth in

¹⁰ "Certain Defendants" are Alcon Laboratories, Inc., Biogen Idec Inc., Endo Pharmaceuticals Inc., MedImmune, Inc., Takeda Pharmaceuticals North America, Inc., and UCB, Inc. These Defendants also submit supporting affirmations of counsel (*see* Schlant Affirmation; Banas Affirm.; Styka-Bloom Affirm.; Mooney Affirm.; Sullivan Affirm.; and Hagerty Affirm.).

detail the fraudulent scheme involving all defendants” (Plaintiff’s Memo of Law at 49, quoting *Niagara Mohawk Power Corp. v Freed*, 265 AD2d 938, 939 [4th Dept 1999]).

The Court notes, however, as stated by the Certain Defendants’ Reply Memo, that the fraudulent scheme alleged by Plaintiff is not the typical conspiracy of all players agreeing to act in a certain way, whereas Defendants here, constituting major players in the pharmaceutical industry, are competitors alleged to have competed against each other for greater market share through marketing of the “spread”. Thus, the cases cited by Plaintiff are not on point.

Nevertheless, the Verified Complaint does lay out the labyrinth of a unique picture of a number of companies that, Plaintiff alleges, took advantage of a legislative neglect or inability to define the term “average wholesale price”. Further, Plaintiff alleges that Defendants independently overcharged the taxpayers through a secretive scheme behind Medicaid reimbursements.

As stated several times already in this Decision, apparently unlike in Federal court, a State court must permit a plaintiff in a complex case like this one involving many defendants extensive discovery of information peculiarly in the possession of defendants, before dismissing claims that defendants contend must be filled out with evidentiary facts; in other words, discovery must proceed (*see Lanzi v Brooks*, 43 NY2d at 780; *Jered*, 22 NY2d at 194; *cf. United States ex rel. Harris v Bernad*, 275 FSupp2d 1, 7-8 [D DC 2003] [“[i]n cases where the complaint alleges complex or extensive fraud schemes, courts often relax the Rule 9(b) standard”]). The separate application of Certain Defendants to dismiss, is denied.

d. Separate Application by Novartis Pharmaceuticals Corporation and Others

Defendant Novartis Pharmaceuticals Corporation (NPC) contends in a separate application that the allegations against it in the Verified Complaint are particularly deficient because they fail to identify any NPC drug for which there were purportedly fraudulent AWP's (see Novartis Memo of Law at 1, 3 n.2).¹¹ The only two drugs the Verified Complaint ascribes to NPC are Fluoxetine HCL and Atenolol, which NPC denies are its products (see *id.* at 3. n.2, citing Thompson, *Physicians Desk Reference* 103, 110 [5th Ed 2005]; Conley Affid., sworn to on Mar. 26, 2006 [photocopy] ¶ 5). Both Fluoxetine HCL and Atenolol are generic drugs, and NPC claims that it does not market or sell generic drugs to wholesalers, retailers or providers (see Conley Affid. ¶ 5).

Plaintiff responds that it is irrelevant whether a single specific example of a drug for which the County was overcharged as a result of Defendants' fraud is pleaded in the Complaint, because the examples are merely illustrative (see Plaintiff's Memo of Law at 50).

With respect to NPC specifically, however, the Court notes that NPC resulted from a merger of Ciba-Geigy and Sandoz in 1996 (see Kent, "The Return of Corrective Advertising", Vol 222, No. 37, 8/20/99, NY Law J., 3 col. 1).¹² Thus, the supplemental application to dismiss NPC from the suit is denied for the reasons stated herein, under part C (10) (Sandoz).

¹¹ Each of the following Defendants join in NPC's separate application: Agouron Pharmaceuticals, Inc., Greenstone, LTD, and Par Pharmaceutical, Inc. NPC also joins in and incorporates into its separate application the Joint Motion to Dismiss (see NPC Memo of Law at 1).

¹² Further, NPC is alleged to have been the subject of investigations by the House Committee on Energy and Commerce and the Office of Inspector General of HHS (see VC ¶¶ 260-261). Note that, because Sandoz markets generic drugs, NPC's claim that it does not sell generic drugs is disingenuous.

With respect to Par Pharmaceuticals, Inc., the Verified Complaint alleges that the County spent over \$200,000 on Par's Fluoxetine HCL in 2002, for which the County alleges it was overcharged at least 90 percent for the most popular dosage, based upon a false AWP. In addition, Par has been investigated by the Commonwealth of Massachusetts and by the House Energy & Finance Committee (*see* VC ¶¶408-410). The allegations against Par are sufficient to sustain the causes of action against it.

With respect to the two other Defendants joining NPC's supplemental application, Agouron and Greenstone Ltd., both are subsidiaries of Pfizer, Inc., the latter of which produces Lipitor, a drug dispensed under Medicaid during the period in question in Erie County (*see* VC ¶ 188). However, no drug specifically marketed or sold by Agouron or Greenstone is alleged in the Verified Complaint, and therefore, the Court dismisses all causes of action against Agouron and Greenstone, with leave to Plaintiff to replead within thirty (30) days of service of notice of entry of an order.

e. Separate Application by Immunex Corp.

Immunex Corp. (Immunex) files a separate application, in addition to joining the Joint Motion, to address two issues specific to it. Initially, Immunex asserts that there are no specific allegations in the Verified Complaint against it except with respect to Leucovorin Calcium, which is a physician-administered drug that, under New York law, is not reimbursed on the basis of AWP (*see* Immunex Memo of Law at 1-3, citing SSL § 367-a [9][a]). Secondly, Immunex asserts there are allegations against Amgen, Inc., which acquired Immunex in July 2002, but that Immunex cannot be held liable for the actions of Amgen (*see* Immunex Memo of Law at 2, citing *Murray v. Miner*, 74 F3d 402, 404 [2nd Cir 1996] [single employer doctrine]). Plaintiff does not

appear to contest either contention, but nonetheless states that Immunex should be held in the Complaint with respect to any drugs sold on the basis of AWP.

The Court dismisses the remaining causes of action against Immunex alone, with leave to Plaintiff to replead within thirty (30) days of service of notice of entry of an order, as to any other Immunex drugs and/or liability for actions of Amgen, if any (of which there are no allegations in the instant Verified Complaint).

f. Separate Application by Purdue Pharma L.P.

Purdue Pharma L.P. (Purdue) submits a supplemental application, in addition to joining in the Joint Motion, on the basis that the Verified Complaint does not identify any specific Purdue drug that supports Plaintiff's claims (*see* Purdue Memo of Law at 1). For the same reason that the claims against Immunex were dismissed, the Court dismisses all claims against Purdue with leave to Plaintiff to replead within thirty (30) days of service of notice of entry of an order.

g. Separate Application by Hoffmann-La Roche Inc. and Roche Laboratories Inc.

Hoffmann-LaRoche Inc. (Hoffmann-LaRoche) and Roche Laboratories Inc. (Roche Labs) submit a separate application, in addition to joining the Joint Motion, to assert that all causes of action against them must be dismissed. Initially, Hoffmann-LaRoche asserts that the Verified Complaint alleges no drugs sold by it, while Roche Labs asserts that the Verified Complaint alleges only one specific drug sold by it, Invirase (*see* VC ¶¶66, 90, 318-321). In addition, although Plaintiff alleges investigations by Congress of Hoffmann-LaRoche, Hoffmann-LaRoche contends that those investigations revealed no wrong-doing by Roche or Hoffmann-LaRoche (*see* Styka-Bloom Affirm. ¶¶6, 12 & n.1). Hoffmann-LaRoche invites the Court to take judicial

notice of a House Committee on Energy & Commerce investigation (*see id.* ¶ 12, citing *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*: Hearing Before the Subcomm. on Oversight & Investigations, 108th Cong. 126, at 2 [2004]).¹³

In any event, Hoffmann-LaRoche and Roche Labs also rely upon the dismissal of all claims against Hoffmann-LaRoche in the AWP MDL class action (*see In re AWP MDL*, no. 1456, 307 FSupp2d 196, 209-210 [D Mass Feb. 24, 2004]). In that case, the Court considered motions to dismiss various federal claims, including racketeering and anti-trust actions, against many defendants including Hoffmann-LaRoche. The Court determined that there were insufficient allegations to support a claim of a fraudulent scheme including Hoffmann-LaRoche, in part because it was “the only Defendant for which no examples of allegedly-incriminating communications, fraudulent pricing, or governmental investigations were given” (*id.* at 209). The Court dismissed the claims against Hoffmann-LaRoche, stating that the pleading was not particular enough to infer that Roche engaged in racketeering and denied the plaintiff’s discovery with respect to Roche (*id.* at 210).

Although it is not clear that the AWP MDL decision has any parallel to the instant action involving only State claims, Plaintiff fails to shed light on the issue, stating only that discovery will shed further light on the allegations against both Hoffmann-LaRoche and Roche Labs.

¹³ Although Hoffmann-LaRoche and Roche Labs contends that Plaintiff cannot allege that any governmental authority has found that they engaged in any wrongful activity regarding their pharmaceutical pricing, to clarify the record, however, the Court notes that one subsidiary/branch of Roche Group, F. Hoffmann La-Roche Ltd., paid a large fine to settle conspiracy and price fixing allegations concerning vitamin additives in 1999 (*see* www.usdoj.gov, “F. Hoffmann La-Roche and BASF Agree to Pay Record Criminal Fines for Participating in International Vitamin Cartel [Press Release May 20, 1999]).

The Court determines that there are the bare bones of sufficient allegations against Roche Labs, and its supplemental application to dismiss is denied. The Court also determines, however, that all causes of action against Hoffmann-LaRoche Ltd. are dismissed with leave to replead within thirty (30) days of service of notice of entry of an order.

h. Separate Application by AstraZeneca Pharmaceuticals LP

Defendant AstraZeneca Pharmaceuticals LP (AstraZeneca) submits individual papers setting forth additional grounds for dismissal specific to it, as well as joining in with Joint Defendants' motion papers (*see* White Affid. ¶ 3). In 2003, AstraZeneca entered into a Corporate Integrity Agreement (CIA) with the HHS/OIG (*see* White Reply Affid., Exhibit A). Simultaneously, AstraZeneca also entered into a settlement agreement with the State of New York, addressing the State's claims against AstraZeneca for allegedly violating various statutes and the common law from January 1991 through 2003, involving the marketing, sale and pricing of Zoladex for treatment of prostate cancer, by knowingly and willfully offering and paying illegal remuneration to physicians and others (*see* White Affid., Exhibit A [hereinafter NY Settlement Agreement], ¶ F, at 2-3 [executed by AstraZeneca on Dec. 3, 2003]). The NY Settlement Agreement provides in pertinent part:

the state of New York, on behalf of itself and its officers, agents, agencies and departments, releases and discharges Zeneca, its predecessors, successors [et al.] from any civil or administrative claims for Medicaid damages or penalties that the state *** has or may have relating to the Covered Conduct as defined in Preamble Paragraph F. The payment of the Settlement Amount [of \$4,931,188.86, plus interest] fully discharges Zeneca from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the state * * * for the Covered Conduct

(NY Settlement Agreement ¶ III (2), at 7).

AstraZeneca contends that, to the extent that the allegations in the Verified Complaint apply to Zoladex, they are within the scope of the conduct covered by the settlement release (*compare* AstraZeneca Memo of Law, at 4, citing Verified Complaint ¶¶1-19, 116-122, 156-158, 223-227 & 229 with NY Settlement Agreement Preamble ¶ F, at 2-4 [“Covered Conduct”]).

Plaintiff does not contest AstraZeneca’s contention that it has settled and is released from liability for fraudulently reporting AWP’s for Zoladex from January 1991 through December 3, 2003 (*see* Plaintiff’s Memo of Law at 52). Thus, any claims against Astra Zeneca based upon sales of Zoladex from January 1991 through December 2, 2003 are hereby dismissed with prejudice.

However, Plaintiff notes that the NY Settlement Agreement preserves certain claims, to wit:

Notwithstanding any term of this Agreement, the state of New York specifically does not herein release any person or entity, including Zeneca * * * from * * * (c) any liability to the state of New York (or any agencies thereof) for any conduct other than the Covered Conduct; * * *(j) any reporting of AWP for Zoladex to First Data Bank or any other national reporting service for use in Medicaid reimbursement submitted *subsequent to the effective date of this Agreement*

(NY Settlement Agreement ¶ III (3), at 7-8 [emphasis supplied]).

AstraZeneca contends in its Reply Memorandum, that pursuant to the CIA it executed, it is required to provide to the State of New York, among others, Average Sale Prices for its Medicaid prescribed drugs calculated in a way to account for “the very factors that Plaintiff alleges should have been included” (*see* AstraZeneca Reply Memo of Law at 3; White Reply Affid. Exhibit A, at ¶ III.D). The implication is that AstraZeneca could not now be liable for inflated AWP’s, because of the reporting requirements.

In the Court's view, the fact that AstraZeneca has been required to report its pricing activities to the State – or even that it agreed in the Settlement Agreement to follow State and Federal Medicaid law – does not, contrary to its contention, negate Plaintiff's causes of action against it. However to the extent that Plaintiff propounds notices to produce or interrogatories to AstraZeneca for information or documents and the like that it has already produced to the State, AstraZeneca may simply produce to Plaintiff that information.

Thus, to the extent that the Verified Complaint alleges claims against AstraZeneca based upon actions taken by it with respect to Zoladex after December 3, 2003, those claims survive, and the separate application, insofar as it seeks to dismiss them, is denied. The issues may more properly be addressed in a motion for summary judgment.

In addition, the separate application of Astra Zeneca to dismiss causes of action which remain pending against AstraZeneca with respect to any other drugs reimbursed by Erie County through Medicaid besides Zoladex, is denied.

i. Separate Application by Bayer Corporation

Bayer Corporation (Bayer) submits a supplemental application to dismiss, in addition to joining the Joint Motion, to raise issues concerning a January 2001 Settlement with the State of New York (*see* Africano Affirm., Exhibit A, State Settlement Agreement [hereinafter 2001 Settlement]). This settlement is referenced in the Verified Complaint (*see* VC ¶¶352-355). The Verified Complaint alleges that, in 2002, Bayer agreed to pay a sum of \$14 million to the United States and forty-five (45) individual states to settle allegations under the federal False Claims Act (*see* 31 USC § 3729 *et seq.*) that Bayer falsely inflated AWP's and other standards for reimbursement under Medicaid, i.e. setting a high AWP while selling the product to doctors at a

dramatic discount, thus inducing doctors to buy more of its products and increasing its market share (*see* VC ¶¶352-354). Bayer also entered into a five-year Corporate Integrity Agreement with HHS/OIG under which it agreed to conduct itself in a certain way and is under certain reporting requirements (*see id.* ¶ 355), with respect to each drug Bayer sells that will be subject to reimbursement under the State's Medicaid program (*see* 2001 Settlement ¶ III (8), at 9).

The 2001 Settlement reports that the State asserted civil claims against Bayer under State statutes and the common law based upon alleged inflation of AWP's of certain drugs during the period from January 1993 through August 1999 (hereinafter the "Qui Tam" Drugs). Bayer was also alleged to have intentionally misreported and underpaid its Medicaid Rebates for the "Qui Tam" drugs under the Medicaid Rebate Program (42 USC § 1396r-8) (*see* 2001 Settlement, ¶¶II (C) (i-iv) (the "Covered Conduct") [among other conduct]). Bayer denied all such contentions (*see* 2001 Settlement, ¶ II (E), at 4). Bayer simultaneously settled with the United States regarding the Covered Conduct, entered into a CIA and paid \$14,000,000, of which New York's share was over \$1.3 million (*see* 2001 Settlement ¶ II (H), III (1)(a), at 4-5). The parties provided mutual releases, but the State reserved "any civil * * * liability that BAYER has or may have under any State statute, regulation or rule not released in Paragraph III (2) above", i.e. releasing only claims concerning the Covered Conduct (*see* 2001 Settlement ¶ III (2), (5) - (6), at 7-8).

In addition, Bayer notes that the only one of its drugs that the Verified Complaint cites is Cipro, and that the Verified Complaint alleges inflated AWP's for Cipro only in 2002. Bayer asserts that any claims based upon post-settlement sales of Cipro or any other Bayer product must be dismissed for failure to state a claim (*see* Bayer Memo of Law at 4). In seeking to dismiss all claims against it, Bayer relies specifically on the fact that the 2001 Settlement also requires it to

comply with detailed price reporting obligations, i.e. report the "average sales price" (ASP) for every drug that it sells in the United States (see *Africano Affirm.*, Exhibit A, at 9). Because of that, Bayer contends, Plaintiff cannot sue Bayer for failure to include discounts, rebates and other price concessions in its calculation and reporting of AWP's (see *Bayer Memo of Law* at 3).

Plaintiff responds that it is entitled to explore through discovery Bayer's compliance with the 2001 Agreement's price reporting obligations, both post-2001 and prior to 2001, presumably for any drugs/activities not covered by the settlement, such as Cipro.

To dismiss all claims against Bayer on the requested basis would require the Court to assume that, as of 2001, Bayer reported accurate "average sales prices" (ASPs) that were unaffected by any alleged inflation of AWP's for Cipro prior to 2001. Such assumptions cannot be made at the pleading stage. Cipro was not one of the "Qui Tam" drugs and its sales do not appear to fall under the Covered Conduct in the 2001 Settlement.¹⁴

¹⁴ In June 2006 and August 2006, Bayer submitted Supplemental Authority in support of its motion to dismiss, a decision by a Kentucky Court (*Kentucky v Alpha, Inc.*, Case No. 04-C1-148 [June 23, 2006]) and the report of Special Masters in the *State of Mississippi v Abbott Laboratories, Inc.* (Chancery Ct. Hinds County July 28, 2006) (see Notices of Supplemental Authority, filed June 2006, Exhibit A, and filed August 9, 2006, Exhibit A). With respect to each case, Bayer has also submitted copies of the Settlement Agreements with the respective states which Bayer asserts are identical to the Agreement with the State of New York (see *id.* at 1-2 & Exhibits B). The Court rejects these submissions as bases for the motion to dismiss in the instant case. For example, in the Mississippi report of Special Masters, all claims against Bayer for any drugs both before and after the settlement were dismissed. However, the situation was dissimilar: in the Mississippi action, there were no allegations about any drugs other than the Qui Tam drugs, and the report specifically permitted the State to come back should other allegations concerning other drugs turn up in the future (see Report at p. 3-4). In addition, the State asserted that, given Bayer had made quarterly ASP reports for each of its drugs, any post settlement claims were moot. The Court finds such assumptions unwarranted in the instant case, given Bayer's history as reported in the Verified Complaint.

Therefore, as with AstraZeneca, the Court determines that, to the extent that Plaintiff propounds notices to produce or interrogatories to Bayer for information that it has already produced to the State under the 2001 Settlement, Bayer may simply produce to Plaintiff that information.

To the extent that the Verified Complaint alleges claims against Bayer based upon actions taken by it with respect to Cipro sales in 2002, Plaintiff alleges, and the Court agrees, that those claims should survive, and the separate application insofar as it seeks to dismiss those claims is denied. The issues may more properly be addressed in a motion for summary judgment.

Any claims against Bayer based upon sales of the "Qui Tam" drugs during the period from January 1993 through August 1999 are hereby dismissed with prejudice.

The separate application of Bayer insofar as it seeks to dismiss all causes of action against it is denied with respect to any other drugs reimbursed by Erie County through Medicaid besides the Qui Tam Drugs and/or the Covered Conduct (see 2001 Settlement, ¶ II (C) & 6-7 [listing "Qui Tam" drugs and "Covered Conduct"]).

j. Separate Application by Sandoz, Inc.

Sandoz, Inc. submits a separate supplemental memorandum of law. Its application contends that the Verified Complaint must be dismissed to the extent that Plaintiff's claims involved Medicaid reimbursements for drugs categorized as "multiple source generic drugs" (hereinafter "generic" drugs).¹⁵ Sandoz contends that Plaintiff's fraud-based causes of action fail

¹⁵ Sandoz's supplemental memorandum is joined by eighteen (18) Defendants: Abbott Laboratories, Inc., Alpharma, Purpac, Barr Laboratories, Inc., Ben Venue Laboratories Inc., Boehringer Ingelheim Roxane, Inc. (f/k/a Roxane Laboratories Inc.), Dey, Inc., ETHEX Corp., Ivax Pharmaceuticals, Inc., Mylan Laboratories Inc., Mylan Pharmaceuticals Inc., Par Pharmaceuticals Inc., UDL Laboratories,

to state a claim to the extent that the reimbursements under Medicaid were not based upon AWP, in part because that is the only basis Plaintiff has alleged (*see* Sandoz Memo at 1). Sandoz contends that, to the extent that Plaintiff paid Medicaid reimbursements for any products reimbursed at the Federal Upper Limit (FUL) or other formula allegedly not involving AWP, there can be no connection between the alleged fraud of reporting false AWPs and the purported injury, i.e. reimbursing pharmacies too much for – in this case – generic drugs (*see* Sandoz Memo at 2).

Plaintiff responds that, regardless whether a generic multi-source drug has an FUL set for it, the reimbursement for the drug originates nonetheless in an AWP, and the Verified Complaint so alleges (*see* Plaintiff's Memo of Law at 45, citing VC ¶110). In other words, the FUL is set at 150 percent of the lowest reported price, for generic drugs with at least three suppliers. Thus, Plaintiff is alleging that, knowing that the reported prices will serve as the basis for FUL, Defendant generic drug manufacturers report their prices accordingly (*see* VC ¶¶139-140).

At a hearing before the United States House of Representatives Committee on Energy and Commerce's Subcommittee on Oversight and Investigations, entitled "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much" (Serial No. 108-126 [Dec. 7, 2004]),¹⁶ the Hon. Joe Barton stated:

Inc., Pharmacia Corp., Greenstone LTD, Teva Pharmaceuticals USA, Inc., Warrick Pharmaceuticals Corp., and Watson Pharmaceuticals, Inc. (*see* Sandoz Memo of Law at 1, n.1). Each of these Defendants also joins in the Joint Defendants' Memoranda (*id.*).

¹⁶ Defendants Hoffmann-LaRoche and Roche Labs requested that the Court take judicial notice of the hearing record cited (*see* Styka-Bloom Affid. ¶ 6, 12 & n. 1).

* * * The existence of substantial spreads remains a fixture of Medicaid prescription drug reimbursement.

Generic manufacturers initially set the AWP of their product at 89.9 percent of the brand name's AWP. In the words of one manufacturer, we "set it and forget it." Meanwhile, fierce competition drives down the actual sales price of these generics, therefore increasing the spread, often dramatically.

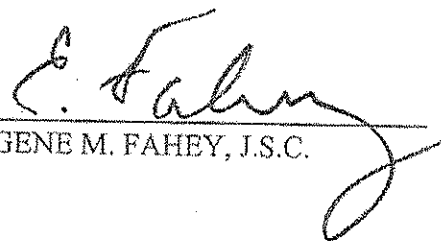
I want to be clear here that the price competition is a good thing. Generic drugs have a critical role in [sic] play in containing soaring drug costs. Concern, however, is that because of AWP the Medicaid program all too often misses out on these cost savings. Medicaid's use of AWP corrupts the market and turns what would otherwise be a positive development, namely price competition, into abuse that deprives Medicaid of the benefits.

The primary beneficiaries of the current Medicaid reimbursement structure are the retail pharmacies. Data obtained by the committee from five of the largest retail pharmacy chains reveals that during the period of July 1, 2002 to June 30, 2003 the average acquisition cost for seven widely prescribed generic drugs was 22 cents, while the average Medicaid reimbursement just for those drugs alone was 56 cents, more than double the cost * * *

(*id.*).


Sandoz is correct that the Complaint does not spell out the specifics of the relationship between AWP and the reimbursements for generic drugs under Medicaid. The details should become clear during discovery. The separate application of Sandoz is denied.

Plaintiff to submit an order on notice to Defendants.


EUGENE M. FAHEY, J.S.C.

Dated: September 7, 2006

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CAROL M. WILLIAMS
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